



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/743,781

03/28/2001

Daniel Paris

12062.105014

7516

20786 7590 11/06/2008

KING & SPALDING LLP
1180 PEACHTREE STREET
ATLANTA, GA 30309-3521

EXAMINER

ANDERSON, JAMES D

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

11/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/743,781	Applicant(s) PARIS ET AL.	
	Examiner JAMES D. ANDERSON	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 23-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/30/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1614

DETAILED ACTION

Formal Matters

Applicants' response and amendments to the claims, filed 7/30/2008, are acknowledged and entered. Claim 22 has been cancelled by Applicant. Claims 1, 3, and 23-30 are pending and under examination.

Response to Arguments

Any previous rejections and/or objections to claim 22 are **withdrawn** as being moot in light of Applicant's cancellation of the claim.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 7/30/2008. The Examiner has considered the references cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

Priority

Applicant's arguments regarding the priority date afforded the instant claims are persuasive. Accordingly, the claims are afforded a priority date of **July 13, 1998**.

Claim Rejections - 35 USC § 112 – 2nd Paragraph – New Ground of Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 27-29 recite the limitation "...wherein the secretory phospholipase A2 inhibitor..." in lines 1-2 of each respective claim. There is insufficient antecedent basis for this limitation in the claims. This rejection is necessitated by Applicant's amendment to claim 1

Art Unit: 1614

(from which claims 27-29 depend), wherein the limitation "a secretory phospholipase A2 inhibitor" was deleted and replaced with "oleyloxyethylphosphocholine".

Claim Rejections - 35 USC § 112 – 1st Paragraph – New Ground of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 3, and 23-30 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for modifying beta-amyloid-induced vasoactivity comprising administering oleyloxyethylphosphocholine, does not reasonably provide enablement for modifying beta-amyloid-induced vasoactivity comprising administering other sPLA2 inhibitors, is **withdrawn** in light of Applicant's amendments.

Claims 1, 3, and 23-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

In the claim amendments filed 10/1/2004, Applicants amended claim 1 to recite the limitation "in an amount ranging from between 0.1 ng to 10 mg/kg body weight/day". Support for this amendment was alleged to be found at page 15, lines 8-9 of the specification. However, at page 15, lines 8-10 of the specification, Applicants disclose that the quantity to be administered will vary for a patient and will vary from about 100 ng/kg of body weight to 100 mg/kg of body weight per day and preferably will be from 10 µg/kg to 10 mg/kg per day. Thus, while the specification provides written basis for the upper limit of 10 mg/kg/day, no support is found for the lower limitation of 0.1 ng/kg/day (*i.e.*, 100 µg/kg/day) as recited in instant claim 1.

Accordingly, the limitation "in an amount ranging from between 0.1 ng to 10 mg/kg body weight/day" submitted in the claim amendments filed 10/1/2004 introduce new matter into

Art Unit: 1614

claims because no support for the lower limit of 0.1 ng/kg/day is found in the specification or originally filed claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1, 3, 23, 24, and 27-30 under 35 U.S.C. 102(b) as being anticipated by Watanabe (WO 99/25340; Published May 27, 1999), is **withdrawn** in light of Applicants' amendments. Further, the reference no longer qualifies as prior art under 35 U.S.C. 102(b) in view of Applicant's priority date of July 13, 1998.

The rejection of claims 1, 3, 23, 24, and 27-30 under 35 U.S.C. 102(e)(2) as being anticipated by Watanabe (USP No. 6,436,983; Issued Aug. 20, 2002; Filed Nov. 14, 1998), is **withdrawn** in light of Applicants' amendments. Further, the 371 date of the reference is Apr. 10, 2000 and thus does not qualify as a 102(e) reference against the pending claims, which have priority to July 13, 1998.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

Art Unit: 1614

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614